K071621

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT - 9 2007

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Dan Marinsik
Reliant Technologies, Inc.
464 Ellis St.
Mountain View, CA 94043
650 605-2237
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NAME OF DEVICE

Trade Name:	Reliant Technologies C300 Chiller System
Common Name:	Skin Refrigerant
Regulation Number	878.4810
Product code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

LEGALLY MARKETED PREDICATE DEVICES

Name: Paradigm-Trex, LLC, DermaChiller 4
510(k) #: K014253

Name: MedArt Corporation, MedArt 520 Cooling System
510(k) #: K000503

DEVICE DESCRIPTION

The C300 Chiller System is a thermoelectric cooler (TECs) which utilizes the Peltier effect. The chiller employs solid-state heat pumps that cool thermoelectrically and contain no moving parts. The C300 Chiller System is contained within a single housing. The chiller console is electrically connected to a standard 110 VAC wall outlet. The unit delivers low temperature air at an adjustable rate through a treatment tube.

The user interacts with the C300 Chiller System by turning the power switch to the on position and selecting the desired temperature via the display on the digital controller

INDICATION FOR USE STATEMENT

The Reliant Technologies C300 Chiller System is intended for use in:

Skin cooling in conjunction with drmatological laser treatments to reduce pain and thermal damage to skin tissue.

SUBSTANTIAL EQUIVALENCE COMPARISON

Indications for Use

Substantial equivalence for the Reliant Technologies C300 Chiller System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indication statements.

Clinical Performance Data

Sufficient safety data has been gathered to determine that the Reliant Technologies C300 Chiller System performs as clinically intended and that no new issues of safety and effectiveness are introduced.

Technological Characteristics

Key technological characteristics of the Reliant Technologies C300 Chiller System, such as cooling capacity, are equivalent to the Paradigm-Trex, LLC, DermaChiller 4 as described in submission K014253 and the MedArt Corporation, MedArt 520 Cooling System as described in submission K000503.

CONCLUSION

Based on the design, materials, function, intended use and clinical evaluation, the Reliant Technologies C300 Chiller System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. No changes are being made in the laser wavelength or operating principle. Safety and effectiveness are reasonably assured, justifying 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2007

Reliant Technologies, Inc.
% Mr. Dan Marinsik
Senior Director, Clinical
Regulatory, & Quality
464 Ellis Street
Mountain View, California 94043

Re: K071621
Trade/Device Name: Reliant Chiller System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 31, 2007
Received: September 05, 2007

Dear Mr. Marinsik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND/GSDB
D.O.
f/t:SPB:kxl:10-3-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K071621

Device Name: Reliant Chiller System

Indications for Use:

The Reliant Chiller System is intended for use in:

Skin cooling in conjunction with dermatological laser treatments to reduce pain and thermal damage to skin tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071621